NIH IRP Clinical Trial Orientation Series
October 2015

Day 1: October 7, 2015
Natcher Conference Center, Room F1/F2

8:30 AM – 9:15 AM	**Overview of NIH** *Elizabeth Ness, RN, MS*
9:15 AM – 10:15 AM	**Good Clinical Research Practice and Human Subject Protection** *Tammy Yokum, RN, MSN*
10:15 AM – 10:30 AM	***Break***
10:30 AM – 11:30 AM	**Clinical Trial Design** *Georgie Cusack, RN, MS, AOCNS®*
11:30 AM – 12:00 PM	**Subject Recruitment** *Elizabeth Ness RN, MS*
12:00 PM – 1:00 PM	***Lunch***
1:00 PM – 2:15 PM	**Protocol Development, Review and Approval Process** *Tammy Yokum, RN, MSN*
2:15 PM – 2:30 PM	***Break***
2:30 PM – 4:00 PM	**Drug Development and U.S. Regulatory Oversight of IND Clinical Trials: Role of the FDA and the Sponsor** *Elizabeth Ness, RN, MS*

Day 2: October 14, 2015
Natcher Conference Center, Room F1/F2

8:30 AM – 9:45 AM	**Role of the Research Team** *Georgie Cusack, RN, MS, AOCNS®*
9:45 AM – 10:45 AM	**Documentation and Document Management in Clinical Research** *Elizabeth Ness, RN, MS*
10:45 AM – 11:00 AM	***Break***
11:00 AM – 12:30 PM	**Informed Consent Process** *Georgie Cusack, RN, MS, AOCNS®*
12:30 PM – 1:30 PM	***Lunch***
1:30 PM – 2:30 PM	**Adverse Events – Part 1** *Elizabeth Ness, RN, MS*

2:30 PM – 2:45 PM	***Break***
2:45 PM – 4:00 PM	**Adverse Events Part 2** **Reportable Events to the IRB** *Elizabeth Ness, RN, MS*

Day 3: October 21, 2015
Natcher Conference Center, Room F1/F2

8:30 AM – 10:00 AM	**Clinical Data Management** *Elizabeth Ness, RN, MS*
10:00 AM – 10:15 AM	***Break***
10:15 AM – 11:30 AM	**Clinical Trial Monitoring** *Tammy Yokum, RN, MSN*
11:30 AM – 12:30 PM	**Q & A** **CT Jeopardy**
12:30 PM – 1:30 PM	***Lunch***
1:30 PM – 4:00 PM	**<u>CENTER FOR CANCER RESEARCH SPECIFIC</u>** **Overview of NCI and Center for Cancer Research (CCR)** **CCR specific operations** **RECIST: Applying the Rules**